

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
INGLIS DURABLE MEDICAL EQUIPMENT Co., INC.**

I. PREAMBLE

Inglis Durable Medical Equipment Co., Inc. (IDME) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, IDME is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by IDME under this CIA shall be three years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) IDME’s final annual report; or (2) any additional materials submitted by [Provider] pursuant to OIG’s request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. “Covered Persons” includes:

- a. all owners, officers, directors, and employees of IDME; and
- b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of IDME.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

IDME shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer.

1. *Compliance Officer.* Within 90 days after the Effective Date, IDME shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of IDME or its parent company, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of IDME or its parent company, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by IDME as well as for any reporting obligations created under this CIA.

IDME shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

IDME shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Within 90 days after the Effective Date, IDME shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. IDME shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. IDME's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. IDME's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with IDME's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of IDME's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by IDME suspected violations of any Federal health care program requirements or of IDME's own Policies and Procedures;
- d. the possible consequences to both IDME and Covered Persons of failure to comply with Federal health care program requirements and with IDME's own Policies and Procedures and the failure to report such noncompliance; and

- e. the right of all individuals to use the Disclosure Program described in Section III.E, and IDME's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by IDME's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

IDME shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 90 days after the Effective Date, IDME shall implement written Policies and Procedures regarding the operation of IDME's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1; and
- b. the Medicare and other Federal health care program rules governing limitations on payment for durable medical equipment for beneficiaries residing in skilled nursing facilities.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), IDME shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall

be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, IDME shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain IDME's:

- a. CIA requirements; and
- b. IDME's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. the Federal health care program requirements regarding the accurate coding and submission of claims;
- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;

- e. the legal sanctions for violations of the Federal health care program requirements; and
- f. examples of proper and improper claims submission practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An IDME employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training .

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* IDME shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Claims Review, Unallowable Cost Review, and any other relevant information.

6. *Computer-based Training.* IDME may provide the training required under this CIA through appropriate computer-based training approaches. If IDME chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, IDME shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist IDME in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this Agreement and the Settlement Agreement.

Each IRO engaged by IDME shall have expertise in the billing, coding, reporting, and other requirements of durable medical equipment industry and in the general requirements of the Federal health care program(s) from which IDME seeks reimbursement. Each IRO shall assess, along with IDME, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze IDME’s coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review), and shall analyze whether IDME sought payment for certain unallowable costs (Unallowable Cost Review). The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

b. *Frequency of Claims Review.* The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

d. *Retention of Records.* The IRO and IDME shall retain and make available to OIG, upon request, all work papers, supporting

documentation, correspondence, and draft reports (those exchanged between the IRO and IDME) related to the reviews.

2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

a. *Discovery Sample*. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of IDME (Discovery Sample).

The Paid Claims shall be reviewed based on the supporting documentation available at IDME's office or under IDME's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix B) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, IDME should, as appropriate, further analyze any errors identified in the Discovery Sample. IDME recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. *Full Sample*. If necessary, as determined by procedures set forth in Section III.F.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to:

(i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at IDME's office or under IDME's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, IDME may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (i) statistically appropriate and (ii) IDME selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from IDME to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. *Systems Review.* If IDME's Discovery Sample identifies an Error Rate of 5% or greater, IDME's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. *Repayment of Identified Overpayments.* In accordance with Section III.I.1 of this Agreement, IDME shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. IDME shall make available to OIG any and all documentation and

the associated documentation that reflects the refund of the Overpayment(s) to the payor.

3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.

4. Unallowable Cost Review. The IRO shall conduct a review of IDME's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether IDME has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by IDME or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. Unallowable Cost Review Report. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether IDME has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

6. Validation Review. In the event OIG has reason to believe that:
(a) IDME's Claims Review or Unallowable Cost Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims

Review results or Unallowable Cost Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the Agreement and/or the findings or Claims Review results or Unallowable Cost Review results are inaccurate (Validation Review). IDME shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of IDME's final Annual Report must be initiated no later than one year after IDME's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify IDME of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, IDME may request a meeting with OIG to: (a) discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Claims Review or Unallowable Cost Review; and/or (c) propose alternatives to the proposed Validation Review. IDME agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review issues with IDME prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to IDME a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Within 90 days after the Effective Date, IDME shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to

enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with IDME's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. IDME shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, IDME shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG, upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health

care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and

ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

2. *Screening Requirements.* IDME shall ensure that all prospective and current owners, officers, directors, employees, contractors, and agents of IDME are not Ineligible Persons, by implementing the following screening requirements.

a. For all prospective owners, officers, directors, employees, contractors, and agents, IDME shall screen such persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. For all current owners, officers, directors, employees, contractors, and agents, IDME shall screen all such persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. IDME shall implement a policy requiring all owners, officers, directors, employees, contractors, and agents of IDME to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) IDME to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If IDME has actual notice that an owner, officer, director, employee, contractor, or agent has become an Ineligible Person, IDME shall remove such person from responsibility for, or involvement with, IDME's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If IDME has actual notice that a person identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, IDME shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, IDME shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to IDME conducted or brought by a governmental entity or its agents involving an allegation that IDME has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. IDME shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money IDME has received

in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, IDME identifies or learns of any Overpayment, IDME shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, IDME shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, IDME shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything that involves:

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If IDME determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, IDME shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of IDME's actions taken to correct the Reportable Event; and

iv. any further steps IDME plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, IDME changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, IDME shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of

change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, IDME shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. a copy of IDME's Code of Conduct required by Section III.B.1;
3. a copy of all Policies and Procedures required by Section III.B.2;
4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
5. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a description of the Disclosure Program required by Section III.E;
7. the following information regarding the IRO(s): (a) identity, address and phone number; (b) a copy of the engagement letter; (c) a summary and description of all engagements between IDME and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting; and (d) the proposed start and completion dates of the Claims Review and Unallowable Cost Review;
9. a certification from the IRO regarding its professional independence and/or objectivity with respect to IDME;
10. a description of the process by which IDME fulfills the requirements of Section III.F regarding Ineligible Persons;
11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
12. a list of all of IDME's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which IDME currently submits claims;
13. a description of IDME's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
14. the certifications required by Section V.C.

B. Annual Reports. IDME shall submit to OIG annually a report with respect to the status of, and findings regarding, IDME's compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
6. IDME's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
7. a summary/description of all engagements between IDME and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to IDME;
9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;
11. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
12. any changes to the process by which IDME fulfills the requirements of Section III.F regarding Ineligible Persons;
13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by IDME in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a description of all changes to the most recently provided list of IDME's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare

Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which IDME currently submits claims; and

16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

(1) to the best of his or her knowledge, except as otherwise described in the applicable report, IDME is in compliance with all of the requirements of this CIA;

(2) he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

(3) IDME has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

D. Designation of Information. IDME shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. IDME shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

IDME:

Kevin W. Jones, Chief Executive Officer
Inglis Durable Medical Equipment, Inc.
2600 Belmont Avenue
Philadelphia, PA 19131
Telephone: 215.581.0700
Facsimile: 215.877.4837

With a copy to:

Paula Sanders Esq.
Post & Schell, P.C.
240 Grandview Avenue
Camp Hill, PA 17011
Telephone: 717.731.1970
Facsimile: 717.731.1985

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of IDME's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of IDME's locations for the purpose of verifying and evaluating: (a) IDME's compliance with the terms of this CIA; and (b) IDME's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by IDME to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of IDME's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. IDME shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. IDME's employees may elect to be interviewed with or without a representative of IDME present.

VIII. DOCUMENT AND RECORD RETENTION

IDME shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for four years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify IDME prior to any release by OIG of information submitted by IDME pursuant to its obligations under this CIA and identified upon submission by IDME as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, IDME shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

IDME is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, IDME and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day IDME fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a written Code of Conduct;
- c. written Policies and Procedures;
- d. the training of Covered Persons;
- e. a Disclosure Program;
- f. Ineligible Persons screening and removal requirements; and
- g. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day IDME fails to engage an IRO, as required in Section III.D and Appendix A.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day IDME fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day IDME fails to submit the annual Claims Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of \$1,500 for each day IDME fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date IDME fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of IDME as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day IDME fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to IDME, stating the specific grounds for its determination that IDME has failed to comply fully and adequately with the CIA obligation(s) at issue and steps IDME shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after IDME receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. IDME may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after IDME fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after IDME receives OIG's written denial of such request or the original due date, whichever is later.

A “timely written request” is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that IDME has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify IDME of: (a) IDME’s failure to comply; and (b) OIG’s exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the “Demand Letter”).

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, IDME shall either: (a) cure the breach to OIG’s satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event IDME elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until IDME cures, to OIG’s satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier’s check, payable to: “Secretary of the Department of Health and Human Services,” and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG’s decision that IDME has materially breached this CIA, which decision shall be made at OIG’s discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by IDME to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by IDME constitutes an independent basis for IDME's exclusion from participation in the Federal health care programs. Upon a determination by OIG that IDME has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify IDME of: (a) IDME's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* IDME shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. IDME is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) IDME has begun to take action to cure the material breach; (ii) IDME is pursuing such action with due

diligence; and (iii) IDME has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, IDME fails to satisfy the requirements of Section X.D.3, OIG may exclude IDME from participation in the Federal health care programs. OIG shall notify IDME in writing of its determination to exclude IDME (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of IDME’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, IDME may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to IDME of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, IDME shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether IDME was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. IDME shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of IDME Corporate Integrity Agreement

this CIA and orders IDME to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless IDME requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether IDME was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) IDME had begun to take action to cure the material breach within that period; (ii) IDME has pursued and is pursuing such action with due diligence; and (iii) IDME provided to OIG within that period a reasonable timetable for curing the material breach and IDME has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for IDME, only after a DAB decision in favor of OIG. IDME's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude IDME upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that IDME may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. IDME shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of IDME, IDME shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, IDME and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of IDME;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of IDME's obligations under the CIA in the event of IDME's cessation of participation in Federal health care programs. If IDME withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, IDME shall notify OIG at least 30 days in advance of IDME's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.
- E. The undersigned IDME signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF IDME

KEVIN W. JONES
Chief Executive Officer

DATE

PAULA SANDERS, ESQ.
Counsel for IDME

DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

LARRY J. GOLDBERG

DATE

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services